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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/698,702 | 10/31/2003 | Charles L. Branch | MSDI-186/PC365.07 | 1925 |

52196 7590 01/17/2008
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| EXAMINER |
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PHILOGENE, PEDRO

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| ART UNIT | PAPER NUMBER |
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3733

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01/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/698,702 | Applicant(s) BRANCH ET AL. | |
| | Examiner Pedro Philogene | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 217-262 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 217-262 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/6/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/02/07 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 217-262 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 63-67,69-89,91-92,94-104 of copending Application No. 09/870,023. Although the conflicting claims are

not identical, they are not patentably distinct from each other because it is clear that all the elements of claims 217-262 are to be found in claims 63-67,69-89,91,92,94-102.

The difference between claims of the '702 application and claims of the '023 application lies in the fact that the '023 application's claims include many more elements and are thus much more specific. Thus the invention o claims of the patent is in effect a "species" of the "generic" invention of claims of the '702 application. It has been held that the generic invention is "anticipated" by the "species". See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the '702 application are anticipated by claims of the '023 application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 230-239,245-249,250-257,259-262 are rejected under 35 U.S.C. 102(e) as being anticipated by Bianchi et al. (6,033,438).

Bianchi et al disclose a spinal implant comprising an elongate bone portion formed fro a cross-sectional bone slice taken from a diaphysis of a long bone having an

outer cortical bone wall surrounding an inner medullary canal, the elongate bone portion having a longitudinal axis or a system including a pair of spinal implants formed of bone (FIGS. 8, 13, 16, 35) including or comprising a first end portion (FIGS. 8, 13, 16, 35) a second bone portion (FIGS. 8, 13, 16, 35) arranged generally opposite the first end portion; a first bone engaging surface (FIGS. 8, 13, 16, 35) and a second bone engaging surface (FIGS. 8, 13, 16, 35) arranged generally opposite the first bone engaging surface; a first sidewall (FIGS. 8, 13, 16, 35) extending between the first and second bone engaging surfaces and including a recess area disposed between the first and second end portions, the recessed area defined by a partial portion of the medullary canal of the long bone and defining a concave outer surface extending along said longitudinal axis between the first and the second end portions from the first engaging surface to the second bone engaging surface; and a second sidewall arranged generally opposite the first side wall relative to the longitudinal axis, the second sidewall extending between the first and second bone engaging surfaces and including a substantially planar outer surface (FIGS. 8, 13, 16, 35) extending along the longitudinal axis between the first and second end portions from the first bone engaging surface to the second bone engaging surface; and wherein the concave outer surface defined by the sidewall is positioned opposite the substantially planar outer surface of the second sidewall relative to the longitudinal axis (FIGS. 8, 13, 16, 35). First substantially planar outer surface adjacent the first end portion and a second substantially planar outer surface adjacent the second end portion, each of the first and second substantially planar surfaces extending between the first and second bone engaging surfaces; and

wherein the concave outer surface extends axially between the first and second substantially planar outer surfaces (FIG. 16B); rectangular cross-section (FIGS. 16A-D), ridges (FIG. 6); engagement features (515, 516).

With respect to the method claims, the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 217-229, 240-244, 258 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Bianchi et al. (6,033,438) in view of Dove et al. (4,904,261)

Bianchi et al disclose a spinal implant comprising an elongate bone portion having a longitudinal axis or a system including a pair of spinal implants formed of bone (FIGS. 8, 13, 16, 35) including or comprising a first end portion (FIGS. 8, 13, 16, 35) a second bone portion (FIGS. 8, 13, 16, 35) arranged generally opposite the first end portion; a first bone engaging surface (FIGS. 8, 13, 16, 35) and a second bone engaging surface (FIGS. 8, 13, 16, 35) arranged generally opposite the first bone engaging surface; a first sidewall (FIGS. 8, 13, 16, 35) extending between the first and second bone engaging surfaces and including concave surface extending along said longitudinal axis between the first and the second end portions.

It is noted that Bianchi et al did not teach of a second sidewall including a convex surface extending along the longitudinal axis between the first and second portions; as claimed by applicant. However, in a similar art, Dove et al evidences (FIGS.3, 4, 6, 7) the use of a spinal implant having convex surface opposite the concave surface to increase the stability of the implant during use.

Therefore, given the teaching of Dover et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Bianchi et al, as taught by Dover et al to increase the stability of the implant during use.

Response to Amendment

Applicant's arguments with respect to claims 217, 218 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's Declaration and Remarks have been considered and noted, however, a new ground of rejection over the references to Bianchi/Dove et al, which antedate applicant's application by at least a year, is made herein above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5,593,409

1-1997

Michelson

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

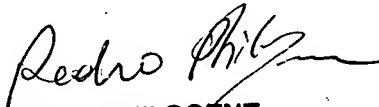
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene
January 15, 2008


PEDRO PHILOGENE
PRIMARY EXAMINER